UNITED STATES DISTRICT COURT
FOR THE
EASTERN DISTRICT OF PENNSYLVANIA

UNITED STATES OF AMERICA *EX REL.* [UNDER SEAL], PLAINTIFF, *v.* [UNDER SEAL], DEFENDANT.	CIVIL ACTION NO. 00-CV-737 (AB) **FILED UNDER SEAL PURSUANT TO 31 U.S.C. § 3730(b)(2)**

COMPLAINT

UNITED STATES DISTRICT COURT
FOR THE
EASTERN DISTRICT OF PENNSYLVANIA

UNITED STATES OF AMERICA *EX REL.* JOSEPH PIACENTILE, PLAINTIFF, *v.* MERCK & CO., INC. and MERCK-MEDCO MANAGED CARE, L.L.C., DEFENDANTS.	CIVIL ACTION NO. _____ **FILED UNDER SEAL PURSUANT TO 31 U.S.C. § 3730(b)(2)**

COMPLAINT

On behalf of the United States of America, plaintiff and relator Joseph Piacentile files this *qui tam* complaint against defendants Merck & Co., Inc. and Merck-Medco Managed Care, L.L.C. (collectively, "Merck-Medco") and alleges as follows:

SUMMARY OF ALLEGATIONS

1. Defendants have systematically defrauded Government-funded health insurance programs by accepting kickbacks in exchange for referring patients to certain products, clandestinely accepting rebates from drug manufacturers in exchange for increasing product market share, secretly increasing long-term drug costs, and failing to comply with state-mandated quality of care standards. Defendants' conduct contravened the express or implied obligations in their contracts with various government agencies to which defendants provide pharmacy benefit management services.

2. Driven by motives unrelated to patient care, defendants' induce physicians to switch patient medications by providing misleading, false or incomplete information that subverts patient care to profit motives. Defendants aggressively seek to substitute or "interchange" physician drug selections pursuant to secret rebate arrangements that defendants have with drug manufacturers. These rebate agreements are nothing more than kickback schemes. Under the rebate agreements, the manufacturers pay defendants to switch patients of government-funded health insurance programs to the manufacturers' own brand of a drug. The arrangement skews the selection of drugs placed on government-funded health insurance programs' lists of preferred drugs and physicians' selection of patient drug therapies. In addition, the schemes result in defendants receiving kickbacks in exchange for referring patients to the manufacturers' drug of choice. In effect, defendants schemed to steer patients to specific drug products in return for compensation based on the volume and dollar value of the referrals.

3. Defendants also secretly increase the cost of drugs provided to beneficiaries by knowingly interchanging patients' medications to prevent them from taking advantage of soon-to-be available generic drugs. By interchanging patients from drugs that, due to the expiration of patents, are expected to have generic equivalents in the near future to drugs that will not have generic equivalents for a longer period of time, defendants cause government-funded health insurance programs to incur additional costs in providing prescription drug benefits.

4. Defendants knowingly violate basic state requirements governing pharmacist supervision of prescription drug fulfillment processes. By failing to meet appropriate

standards of care when providing pharmacy services to beneficiaries of government-funded health insurance programs, defendants compromised the safety and quality of its pharmaceutical operations and violate federal law requiring compliance with such standards.

5. Through their conduct, defendants violate their contracts with government-funded health insurance programs.

INTRODUCTION

6. This is an action to recover damages and civil penalties on behalf of the United States of America arising from false statements and false or fraudulent claims made or caused to be made by the defendants to the United States in violation of the False Claims Act, 31 U.S.C. §§ 3729, *et seq.* (the "FCA"). The false or fraudulent claims and statements at issue involve payments made by Government-funded health insurance programs, such as the Federal Employees Health Benefits Program (FEHBP), TRICARE/CHAMPUS and Medicare to defendants for pharmacy benefit management services and prescription drugs.

7. Originally enacted in 1863, the FCA was substantially amended in 1986 by the False Claims Amendments Act. The 1986 amendments enhanced the Government's ability to recover losses sustained as a result of fraud against the United States.

8. The FCA provides that any person who knowingly submits or causes to submit to the Government a false or fraudulent claim for payment or approval is liable for a civil penalty of up to $11,000 for each such claim, plus three times the amount of the damages sustained by the Government. The Act empowers private persons having

information regarding a false or fraudulent claim against the Government to bring an action on behalf of the Government and to share in any recovery. The complaint must be filed under seal without service on any defendant. The complaint remains under seal while the Government conducts an investigation of the allegations in the complaint and determines whether to join the action.

9. Pursuant to the FCA, relator seeks to recover on behalf of the United States damages and civil penalties arising from false or fraudulent claims supported by false statements that defendants submitted or caused to be submitted to Government-funded health insurance programs.

PARTIES

10. Relator Joseph Piacentile is a resident of New Jersey and a physician. Dr. Piacentile brings this action for violations of the FCA on behalf of himself and the United States pursuant to 31 U.S.C. § 3730(b)(1). He has knowledge of the violations and allegations discussed herein.

11. Defendant Merck & Co., Inc. ("Merck") is a corporation organized, existing and doing business under the laws of the State of New Jersey, with its principal office located at One Merck Drive, Whitehouse Station, New Jersey. Merck is "a global research-driven pharmaceutical company that discovers, develops, manufactures and markets a broad range of human and animal health products, directly and through its joint ventures . . . ." Merck Form 10-K Annual Report (filed Mar. 24 1999). Merck is a global leader in pharmaceutical sales and, together with its subsidiaries, generated sales of almost $27 billion during 1998.

12. Defendant Merck-Medco Managed Care, L.L.C. ("MMMC") is a limited liability company organized, existing and doing business under and by virtue of the laws of the State of Delaware, with its principal office located at 100 Summit Avenue, Montvale, New Jersey. MMMC is a wholly-owned subsidiary of defendant Merck. MMMC is the nation's largest pharmacy benefit management ("PBM") company, managing the prescription benefits of one out of every five Americans. During 1998, MMMC managed over 322 million prescriptions and generated sales in excess of $11.5 billion, primarily through the sale of non-Merck products and pharmaceutical benefit services, principally managed prescription drug programs and programs to manage patient health and drug utilization. *See* Merck & Co., 1998 Annual Report at 26-29. MMMC's business operations are managed and controlled by defendant Merck.

JURISDICTION AND VENUE

13. The Court has jurisdiction over the subject matter of this action pursuant to both 28 U.S.C. § 1331 and 31 U.S.C. § 3732, the latter of which specifically confers jurisdiction on this Court for actions brought pursuant to 31 U.S.C. § 3730.

14. The Court has personal jurisdiction over the defendants pursuant to 31 U.S.C. § 3732(a) because the False Claims Act authorizes nationwide service of process and defendants have sufficient minimum contacts with the United States.

15. Venue is proper in this District pursuant to 31 U.S.C. § 3732(a) because at least one of the defendants can be found, resides or transacts, or has transacted business in the Eastern District of Pennsylvania and/or at least one act proscribed by 31 U.S.C. § 3729 occurred in the Eastern District of Pennsylvania.

ALLEGATIONS

Government-funded Health Insurance Programs

16. Medicare is a federally-funded health insurance program primarily benefitting the elderly that was created in 1965 when Title XVIII of the Social Security Act was adopted. Medicare is administered by the federal Health Care Financing Administration (HCFA). While Medicare does not pay for over-the-counter drugs or most self-administered prescription drugs, it does pay for certain categories of drugs used by Medicare beneficiaries. Under certain circumstances, Medicare Part B covers drugs that are used with durable medical equipment or infusion equipment. Medicare covers certain drugs used in association with dialysis or organ transplantation, chemotherapy and pain management in cancer treatments. The program also reimburses the cost of certain types of vaccines such as those for flu and hepatitis B.

17. TRICARE is the military's health care system, designed to maintain the health of active duty service personnel, provide health care during military operations, and offer health care to non-active duty beneficiaries, including dependents of active duty personnel and military retirees and their dependents. The system operates through various military-operated hospitals and clinics worldwide and is supplemented through contracts with civilian health care providers. TRICARE is a triple-option benefit program designed to give beneficiaries a choice between health maintenance organizations, preferred provider organizations and fee-for-service benefits. Five managed care support contractors create networks of civilian health care providers. Military prescription drug benefits are provide through three programs: military treatment facility outpatient pharmacies, TRICARE

contractor retail pharmacies and a national contractor's mail-order service. In 1997, the military spent approximately $1.3 billion on pharmacy benefits.

18. Defendant Merck-Medco is TRICARE's national mail-order pharmacy program contractor and also serves as the PBM for at least one of TRICARE's regional contractors.

19. The Federal Employees Health Benefits Program (FEHBP) provides health insurance coverage for nearly 8.7 million federal employees, retirees and their dependents. The FEHBP is a collection of individual health care plans, including the Blue Cross and Blue Shield Association, Government Employees Hospital Association and Rural Carrier Benefit Plan. FEHBP plans are managed by the Office of Personnel Management and collectively pay more than $2 billion annually in prescription drug benefits.

20. Defendant Merck-Medco is a contractor that provides pharmacy benefit management services to many FEHBP plans. For instance, the Blue Cross and Blue Shield Association, which operates the largest FEHBP plan, has contracted with Merck-Medco since 1987 to provide mail-order pharmacy services.

The Rise of PBMs

21. The 1990s has seen many changing trends in the health care industry. One of the most significant has been the rise of pharmacy benefit managers. PBMs act as agents for health insurance plans in managing and dispensing prescription drugs in a cost-effective manner. During the early 1990s, pharmaceutical manufacturers — such as defendant Merck — began acquiring PBMs to complement their drug manufacturing operations. By the end of 1995, PBMs owned by pharmaceutical companies dominated

the marketplace, providing services for health plans covering approximately half the population of the United States.

22. PBMs, such as Merck-Medco, provide a number of services to patients and health plans. By their sheer size, PBMs can negotiate discounts on drug prices and streamline the drug delivery process, generating significant savings for health plans. In addition to lowering the cost of providing prescription medications, PBMs have developed disease management programs for specific illnesses, engaged in therapeutic intervention and assisted with formulary development.

23. Therapeutic intervention can take different forms. It may include recommending a generic drug for a brand name drug. Sometimes it involves identifying possible conflicts in drugs prescribed to the same patient or contraindications which may undermine the effectiveness of a prescribed drug. Other times, the PBM's intervention may be intended to persuade a physician to prescribe a different drug than the one initially selected.

24. A formulary is a list of prescription drugs that are preferred by a health plan. Drugs on a formulary may be preferred for therapeutic reasons but also on the basis of cost. As a result, the development of the formulary will affect which drugs are prescribed to health plan patients and, conversely, will affect the sale and market penetration of a drug manufacturer's products.

25. The link between drug manufacturers and PBMs raises significant concerns. For the first time, a single entity controls drug manufacturing, dispensing and distribution through its manufacturing, PBM and pharmacy operations. These relationships raise

developing issues about whether the manufacturer, through its PBM or pharmacy, will improperly steer patients to the manufacturer's drugs, exclude other manufacturers drugs from being delivered to patients or otherwise skew the relationship between the prescribing physician and the patient.

Defendants' PBM Services

26. In November 1993, Merck purchased MMCO, then called Medco Containment Services, Inc. At the time, MMCO's PBM services covered 42 million health plan beneficiaries, a number that had grown to 51 million by the end of 1998. The modest 21% growth in Merck-Medco's "covered lives" has been overshadowed by the immense growth in the number of prescriptions managed by the company and the drug spending it controls. From 1994 to 1998, Merck-Medco increased by 250% its drug spending on behalf of clients, from just over $4 billion to more than $14 billion. During the same period, the company increased the number of prescriptions it managed by almost 200 million, from approximately 125 million to over 322 million, an increase of almost 158%.

27. Defendant MMMC employs approximately 11,000 people, including over 1,700 pharmacists. It delivers pharmaceutical services through a network of 55,000 participating retail pharmacies and through 13 company-operated regional mail order pharmacies in Florida (2), Massachusetts, Nevada, New Jersey, Ohio (3), Pennsylvania (2), Texas (2) and Washington. Merck-Medco's mail-order pharmacy operations serviced 53 million prescriptions in 1998.

28. Merck-Medco has achieved its market prominence and success by streamlining its prescription dispensing operations and honing its ability to interchange

prescriptions. "Interchanging" is the process by which Merck-Medco persuades physicians to prescribe a drug other than the one originally selected. Interchanges may be recommended for medical reasons if Merck-Medco detects that a particular drug is contraindicated for a patients' condition, identifies a problematic drug-drug interaction, or recognizes drug-allergy or drug-age complications. Interchanges also take place for purely monetary reasons, such as switching to a lower cost branded or generic drug or to a drug for which Merck-Medco is being paid a fee — or rebate — in exchange for creating market share growth.

29. To make its services attractive to health plans and other customers, Merck-Medco cut expenses by rearranging traditional pharmacy staffing arrangements and aggressively pursuing interchanging as a means of generating income. By devoting pharmacists traditionally engaged in drug dispensing and filling operations to its interchange program, Merck-Medco generates additional income in two ways. First, it saves money by staffing drug dispensing and filling operations with less expensive, unlicensed pharmacy technicians. Second, it devotes an enormous amount of resources to obtaining lucrative drug interchanges.

30. Merck-Medco routinely interchanges hundreds of drugs manufactured by virtually every major drug manufacturer in the world, including Astra-Zeneca, Bayer, Bristol Myers Squibb, Glaxo Wellcome, Roche, Searle, Pfizer and Parke-Davis. While acting as a "hired gun" in switching any company's brand of drug to another brand, Merck-Medco rarely, if ever, interchanges a drug manufactured by defendant Merck to a drug manufactured by another company.

Merck-Medco Engages in Aggressive Interchanging to Enhance Its Bottom Line

31. Merck-Medco engages in aggressive interchanging as a means of generating millions of dollars in additional income through rebates from drug manufacturers. Drug manufacturers pay Merck-Medco huge sums for giving the manufacturer's drugs preferred status on Merck-Medco's formularies and for improving the market share performance of specific products.

32. Instead of using pharmacists to supervise the prescription filling process as required by state law, Merck-Medco assigns the bulk of its pharmacists to making interchange calls in areas completely apart from where the dispensing operations are performed.

33. Interchanging is so important to Merck-Medco that it has developed an extensive training program for its pharmacists. The goal of the program is to educate pharmacists in speaking skills and the persuasive use of the telephone to improve the chances for obtaining a drug interchange. The program consists of five modules and numerous sample "scripts" for performing interchange phone calls.

34. Pharmacists are carefully trained in speech techniques, the appropriate manner in which to approach a physician, how to formulate their presentation, and how to deal with office staff. They are given lists of words to use and others to avoid. For instance, pharmacists are instructed to say

- "interchange" instead of "switch";
- "more fiscally responsible" instead of "cheaper";
- "drug benefit company" instead of "insurance company"; and

- "patient profile" instead of "computer screen."

One of the program books that Merck-Medco provides to its pharmacists counsels that when a doctor rejects an interchange, "remain polite, respectful, and cheerful. Don't let the rejection upset you. There will be another chance with this doctor — and next time, they may approve the interchange!"

35. Merck-Medco attempts to carefully protect its training programs and interchange manuals. Pharmacists who participate in interchange training have their notes from the training sessions collected and destroyed upon completion of the course. In addition, a binder describing Merck-Medco's interchange program is stored under lock-and-key at all times and is not generally available to the pharmacists making interchange calls.

36. The interchange calls made by pharmacists to physicians fall into two categories: "Re-tagging" and "Proactive calling."

37. Re-tagging is the process by which Merck-Medco attempts interchanges on a retail prescription. When a patient takes a prescription to a retail pharmacy to be filled, the pharmacist contacts Merck-Medco to obtain insurance approval for the transaction. The patient may be waiting of the prescription to be filled or expect it to be filled within a couple of hours. Under such circumstances, Merck-Medco does not have the time needed to contact a physician to obtain an interchange. Instead, Merck-Medco approves filling the prescription as it was prescribed but contacts the physician to obtain approval for an interchange the next time the patient gets the prescription refilled. If approval for the interchange is obtained, the patient's prescription will automatically be renewed using the substituted drug.

38. Proactive calling occurs when Merck-Medco receives a prescription through its mail-order pharmacies. Proactive calling is designed to switch the patient's prescription before it is filled, a goal which mail-order prescriptions facilitate. In fact, it is not uncommon for Merck-Medco to delay filling a mail-order prescription for days while its pharmacists attempt to contact a physician to obtain an interchange.

39. Each of Merck-Medco's thirteen mail-order pharmacies is designed to control and efficiently manage workflow. Each pharmacy is divided into roughly seven areas: mailroom, data entry, filling, protocol, checking, calls and shipping.

40. Merck-Medco's mail order pharmacies generally process prescriptions in the following manner. A prescription is received in the mailroom. It is transferred to data entry where the prescription is entered into the Merck-Medco computer system. A small percentage of prescriptions that have an obvious deficiency — such as an improper or missing quantity — go to the protocol area for follow-up by a pharmacist. Prescriptions that qualify for interchanging are sent to the calling area. Whether or not the interchange is made, the prescription is then sent to filling where the medication is measured, labeled and bar coded by a technician. Once filled, the prescription and medication are sent to checking where the work performed is reviewed by a pharmacist for the first time. The pharmacist verifies the prescription and computer information, as well as the medication provided and label information. Then the completed order is sent to shipping for delivery to the patient.

41. Merck-Medco's system is highly segmented and flexible to permit personnel to be transferred from area to area based on workflow. Pharmacists work in two-hour

patterns, moving to the area where personnel are in greatest demand. As a result, a pharmacist my work for two hours in protocol, two hours in checking and two hours in calling or may spend four hours in calling, depending on daily work requirements.

42. Pharmacists work primarily in protocol, checking and calling. At no time do any pharmacists directly supervise the prescription data entry or medication filling activities that are being performed by technicians. Technicians are directly supervised by non-pharmacists.

43. The vast majority of prescriptions are referred to the calling area. Here pharmacists contact physicians and attempt to obtain permission to interchange medications. Although the success rates for interchanging medications varies, Merck-Medco meticulously tracks the interchange performance of its various call centers. Merck-Medco's Parsippany, New Jersey facility has achieved a 65% interchange rate, the highest rate among all Merck-Medco pharmacies.

44. At any given time, particularly during normal business hours, on-site pharmacists are making interchange calls rather than supervising the prescription filling process.

45. Merck-Medco has begun further streamlining the prescription filling process to the point that a pharmacist never sees the paper prescription written by the patient's physician. Drug filling operations at Merck-Medco's Las Vegas facility are conducted on the basis of computer generated information only, information that is received by the facility from other Merck-Medco locations around the country. Any deviation between the drug information keyed into the computer and the actual written prescription would never be

caught by a pharmacist. This is because only unlicensed technicians perform computer keyboarding and drug filling, and the pharmacists do not have access to the written prescription once the order is sent to Las Vegas for filling. Merck-Medco pharmacists have complained about the "paperless" prescription filling system and, upon information and belief, some have been discharged or have resigned as a result of conflicts relating to Merck-Medco's procedures.

46. Merck-Medco's interchange system is so sophisticated that individual physicians are assigned "screen-out codes" to describe their receptiveness to interchanges. For instance, doctors who refuse to agree to any drug interchanges are coded as "never call," indicating that a pharmacist should not approach the physician about an interchange under any circumstance. Merck-Medco uses dozens of codes to characterize the physicians with whom it deals.

47. Merck-Medco also uses sophisticated techniques to monitor the performance of its pharmacists and their success in achieving drug interchanges.

48. Pharmacists are assigned "personal plan" goals for attaining specific "contact rates" for reaching physicians and "switch rates" for accomplishing interchanges.

49. Pharmacists are routinely provided weekly and/or monthly reports detailing their actual "contact" and "switch" rates compared to their "personal plan" goals.

50. The pharmacists' performance reports detail by drug the number of interchanges handled by the pharmacist, the number of prescriptions that were "screen outs," the number that were "callable," the number of contacts made and the number of switches achieved.

51. The purpose of Merck-Medco's performance monitoring system is to pressure pharmacists to achieve Merck-Medco's aggressive interchange goals and to link pharmacist personnel evaluations and compensation to performance goals.

52. The monitoring system also succeeds in tying pharmacists' performance to overall company goals. This is critical because a portion of the pharmacists' compensation is paid in Merck & Co. stock and/or stock options that become more valuable with the overall success of the company.

53. Merck-Medco's emphasis on switching patients to other drugs causes Merck-Medco and its pharmacists to routinely provide false, misleading or incomplete information to physicians to obtain the interchange.

54. Physicians contacted about an interchange by a Merck-Medco pharmacist are often left with the impression that the interchange is necessary for the prescription to be covered by the health plan. They are not told that the health plan would provide coverage for the drug originally selected by the physician.

55. Physicians are never told that the interchange is being done for purposes of obtaining a rebate from a drug manufacturer or that Merck-Medco is being paid to promote a particular product, even though that is usually the case. As a result, many interchanges occur because physicians do not have all the facts and believe that the interchange is needed to avoid having the patient pay entirely for the prescribed medication.

56. With the exception of its contract with the Department of Defense, most formularies maintained by Merck-Medco for government-funded health insurance programs are "open" formularies, meaning that prescribing "preferred" drugs is voluntary and there

is no penalty for prescribing or purchasing non-formulary drugs. The formularies are often designed to promote those drugs for which Merck-Medco can obtain a rebate or other financial advantage.

57. Although Merck-Medco pharmacists walk a fine line in trying not to directly lie to the physicians, they use a variety of approved buzz words that often shade the truth and provide incomplete information. Pharmacists are trained to tell physicians that the selected medicine is a "non-formulae drug" or that another drug is a "preferred formulae alternative." They often tell the doctor that another drug will result in a "cost benefit to the patient" or that prescribing the suggested drug results in a "cost benefit savings to the patient and the group." Unless the physician asks directly, Merck-Medco pharmacists do not correct the impression that a prescribed drug is excluded from coverage. In fact, absent the rebate being paid to Merck-Medco, defendants' would interchanged few, if any, drugs.

58. Merck-Medco's interchange program is fueled by deceptive and misleading information as a means of furthering a classic kickback scheme. Merck-Medco and, in some instances, its customers, receive kickbacks in the form "rebates" from drug manufacturers. The kickbacks are paid solely for referring patients to the manufacturer's products.

Merck-Medco Increases Drug Costs By Preventing Patients from Receiving Generic Drugs

59. Merck-Medco also seeks interchanges for reasons that profit Merck-Medco and other drug manufacturers while increasing the costs paid by federally-funded health insurance programs. In particular, Merck-Medco routinely attempts to interchange branded

drugs whose patent is set to expire in the near future. Defendants substitute another branded drug that has a patent of longer duration. In the absence of the interchange, the patient's continued use of the original medication would make him or her eligible to begin using a less costly generic drug once the patent on the branded drug expired. However, due to Merck-Medco's intervention, the patient will be placed on an alternate branded drug for a much longer period, increasing long-term drug costs. This type of switch results when Merck-Medco is paid by a single manufacturer to switch a patient from one of its drugs to another of its drugs.

60. Because generic drugs are generally less expensive than their branded counterparts, Merck-Medco's patent expiration interchanges directly cost government-funded health insurance programs millions of dollars in future drug costs.

61. Defendants knowingly engaged in the fraudulent conduct described in this complaint for the purpose of submitting false or fraudulent claims to, and inducing payments from, Government-funded health insurance programs.

62. Although the stated purpose of Merck-Medco's interchange program may be to attain cost efficiencies for its customer health plans and their patients, its true function is to generate hidden profits for Merck-Medco and other drug manufacturers, both in the short and long terms. It is this end that causes Merck-Medco to seek kickbacks from drug manufacturers and falsely and fraudulently induce physicians to prescribe a particular drug that is reimbursable by government-funded health insurance programs or that is being administered by Merck-Medco on behalf the such a program. By tainting the claims submitted to and services performed for government-funded health insurance programs,

Merck-Medco violates the False Claims Act and other federal statutes.

63. Merck-Medco's interchange program is little more than a marketing program designed to give preference and prominence to certain products over other products. It is one more way that a company can generate referrals to its products by having its drug prescribed by a physician to a patient directly. The program gives physicians the impression that preferred drug must be substituted in order to fall within the health plan's formulary coverage. This imprimatur of officialdom makes the interchange program a dangerous marketing tool that carries with it the tremendous possibility for abuse.

64. Merck-Medco's interchange program poses a danger to patients because the hidden rebate payments interfere with the pharmacist's and physician's judgment in determining the most appropriate course of treatment for the patient. Merck-Medco's practices — particularly as they relate to generic drug avoidance — increase the federal government's costs of reimbursing prescription medications.

65. Merck-Medco's interchange program is a kickback scheme. In exchange for referring new patients and physicians to a drug manufacturer's product, Merck-Medco and, in many instances, its customers, received kickbacks in the form of remuneration paid as "rebates" from the manufacturers. These kickbacks distort the prescription drug dispensing system because they are not disclosed to either patients ro physicians when Merck-Medco attempts to explain to the physician why he or she should change the originally prescribed drug to a different Merck-Medco suggested drug.

Merck-Medco Failed to Comply with State Mandated Regulations

66. The staffing and organization of the interchange program results in Merck-

Medco failing to comply with state and federal mandated standards of care for dispensing prescription drugs, thereby threatening patient safety and undermining the integrity of Merck-Medco's pharmacy operations.

67. Government-funded health insurance programs require pharmacies, including Merck-Medco, to comply with state licensing requirements and regulations. By cutting pharmacist staffing in its dispensing and filling operations and segregating pharmacists in other areas, such as interchanging, Merck-Medco runs afoul of regulatory requirements that govern pharmacist supervision of pharmacy technicians. Each of the states in which Merck-Medco operates a pharmacy — Florida, Massachusetts, Nevada, New Jersey, Ohio, Pennsylvania, Texas, and Washington — requires pharmacists to provide some form of direct supervision over the tasks being performed by unlicensed technicians. Most of the states also prescribe specific supervisory ratios that prevent a pharmacist from supervising more than one, two or three technicians as a time.

New Jersey

68. In New Jersey, for instance, only licensed pharmacists or "an apprentice employed in a pharmacy under the immediate personal supervision of a registered pharmacist" can dispense or fill prescriptions. N.J. Stat. Ann. § 45:14-13. State regulations further provide that "[t]he registered pharmacist supervising the activities of supportive personnel shall be physically present in the compounding/dispensing area and shall be personally responsible for the accuracy of the filled prescription." N.J. Admin. Code § 13:39-6.4.

69. "Supportive personnel" is defined as "those persons who perform

pharmaceutical functions under the direct supervision of a registered pharmacist," excluding interns and externs. *Id.* at § 13:39-1.2. "'Direct supervision' means that the registered pharmacist shall be physically present in the compounding/dispensing area where the supportive personnel are performing delegated duties, and shall conduct in-process and final checks of all steps in preparation, compounding, and dispensing of drugs. This supervision shall include, but is not limited to, the checking of each ingredient used, the quantity of each ingredient whether weighed, measured or counted, and the finished label." *Id.* New Jersey state regulations further provide that "[t]here shall be no more than two supportive personnel, not including cashier, stocking and clerical help, being supervised by one pharmacist at any given time. Those personnel who do computer processing of prescriptions are to be included in the 2 to 1 ratio." N.J. Admin. Code § 13:39-6.7(c)

70. "Dispensing pharmacists shall provide direct supervision to supportive personnel who are performing delegated sterile admixture tasks. The ratio of dispensing pharmacists to supportive personnel shall not exceed 1:2 at any given time." *Id.* at § 13:39-11.8(a). "Direct supervision means that the dispensing pharmacist shall be present in the pharmacy dispensing area whenever supportive personnel are compounding sterile admixture products, and shall conduct checks of all steps in preparation, compounding and dispensing of sterile admixture products." *Id.* at § 13:39-11.8(a)(1).

71. Although Merck-Medco's New Jersey pharmacy is careful to maintain a 1:2 ratio of pharmacists-to-technicians *on its premises* at any given time, Merck-Medco fails to comply with the substance of the regulatory requirements. The regulations require

pharmacists included in the ratio to be those that are "dispensing pharmacists" who are providing "direct supervision" to pharmacy technicians and are "present in the pharmacy dispensing area."

Florida

72. Florida law provides that a licensed pharmacist may delegate certain tasks to unlicensed pharmacy technicians, but that "[a]ll such delegated acts shall be performed under the direct supervision of a licensed pharmacist who shall be responsible for all such acts performed by persons under his or her supervision. . . . No licensed pharmacist shall supervise more than one pharmacy technician unless otherwise permitted by the guidelines adopted by the board." Fla. Stat § 465.014.

73. The Florida Board of Pharmacy's regulations require a 1:1 technician-to-pharmacist ratio when "performing professional services." Fla. Admin. Code § 64B16-27.410. The Board "requires that a pharmacy technician be under the direct and immediate personal supervision of a Florida license pharmacist." *Id.* The Board relaxes the technician-to-pharmacist to as high at 3:1 if the technicians perform only certain specified tasks, and the Board preapproves the pharmacy's request to practice with the less restrictive ratio of supervision. *Id.* at § 64B16-27.420.

74. Even with the less restrictive supervision ratio, the Board requires that delegated tasks "must be performed subject to a continuing review and ultimate supervision of the Florida licensed pharmacist who instigated the specific task, so that a continuity of supervised activity is present between one pharmacist and one pharmacy technician." *Id.* at § 64B16-27.430.

Ohio

75. In Ohio, "[o]nly a pharmacist or intern under the personal supervision of a pharmacist is permitted to engage in dispensing and compounding" drugs. Ohio Admin. Code § 4729-5-25. "'Personal supervision' means a pharmacist shall be physically present in the pharmacy and provide personal review and approval of all professional pharmaceutical activities." *Id.* at § 4729-5-01.

76. In order for a technician to assist a pharmacist in Ohio, a system of drug distribution must be carefully designed to compensate for the lack of personal supervision by the pharmacist. In particular, the Board of Pharmacy provides that a person "not a pharmacist or intern under the personal supervision of a pharmacist, may assist a pharmacist in the compounding of prescriptions and dispensing of drugs" but only if "[t]he system of drug distribution must provide exact control and assign immediate responsibility only to a pharmacist accountable at every point in the system between the receipt of the order for a drug and final delivery for administration or use by the patient." *Id.* at § 4729-5-25(B)(2).

Massachusetts

77. The Commonwealth of Massachusetts requires that "[a] registered pharmacist shall not have more than two pharmacy technicians at any one time to assist him or her in filling prescriptions." Mass. Regs Code tit. 247, § 8.02(2). The state relaxes this supervision ratio slightly for more experienced pharmacists, called preceptors. Pharmacist preceptors "shall have nor more than three persons at any one time to assist him or her in filling prescriptions," and one of these assistants must be a pharmacy student

intern. *Id.* at tit. 247, § 8.02(3).

78. In Massachusetts, all pharmacy technicians must work "under the direct supervision" of a registered pharmacist. *Id.* at tit. 247, § 8.02(8).

Nevada

79. In Nevada, a pharmaceutical technician is "a person who performs services in a pharmacy under the direct supervision of a pharmacist." Nev. Admin. Code § 639.010. "Direct supervision" is defined as "the direction given by a supervision pharmacist who is: (a) on the premises of the pharmacy at all times when the persons he is supervising are working at the pharmacy; and (b) aware of the activities of those persons related to the preparation of medications, including the maintenance of appropriate records. *Id.* at § 639.010(4).

80. The Nevada Board of Pharmacy also requires that "[i]n any pharmacy, other than a hospital pharmacy, a pharmacist may not supervise more than two pharmaceutical technicians or two pharmaceutical technicians in training at one time." *Id.* at § 639.250 (temporary regulation, adopted Dec. 1, 1998). Prior to December 1998, the Board restricted a pharmacist to supervising no more than one technician.

Pennsylvania

81. In Pennsylvania, "[a] pharmacy technician may work only under the direct, immediate, [and] personal supervision of a pharmacist." 49 Pa. Code § 27.12(d)(1).

82. "Direct, immediate and personal supervision means that the supervising pharmacist has reviewed the prescription or drug order prior to its being dispensed, has verified the final product and is immediately available on the premises to direct the work

of interns and technicians and respond to questions or problems." *Id.* at § 27.12(b)(2).

Texas

83. In Texas, "[t]he ratio of pharmacists to supportive personnel shall be no greater than 1:2." 22 Tex. Admin Code § 291.32(c)(3). Nonjudgmental technical duties may be delegated by a licensed pharmacist to a technician, but only if the pharmacist "conducts in-process and final checks" and the technician is "under the direct supervision of and responsible to the pharmacist." *Id.* at § 291.32(c)(2)(B); *see id.* at § 291.31(37).

Washington

84. In the State of Washington, pharmacy technicians "may assist in performing, under the immediate supervision and control of a licensed pharmacist, manipulative, nondiscretionary functions associated with the practice of pharmacy." Wash. Admin. Code § 246-901-020(1). "Immediate supervision shall include visual and/or physical proximity that will insure adequate safety controls." *Id.* at 246-901-020(2).

85. Washington requires that "in the preparation of medicine or other materials dispensed to persons not patients within the facility, [there shall be] one pharmacist supervising not more than one pharmacy technician." Wash. Rev. Code 218.64A.040(2); *see* Wash. Admin. Code. § 246-901-130(1). This ratio may only be varied after the pharmacy has filed and received approval for a "pharmacy services plan" that might vary the ratio or change how it is calculated. Wash. Rev. Code 218.64A.040(3); *see* Wash. Admin. Code. § 246-901-130(2).

86. Merck-Medco fails to comply with any of these requirements for supervising unlicensed pharmacy technicians.

87. Merck-Medco pharmacists do not provide "personal supervision," "immediate personal supervision," "direct supervision," or any variation of such concepts to technicians who are preparing and filling prescriptions.

88. Merck-Medco pharmacists are rarely, if ever, physically present in the areas where prescription preparation and filling are being completed.

89. Moreover, Merck-Medco pharmacists never perform in-process checks of the preparation and dispensing activities as required by various state regulations.

90. By permitting its clerical and technical personnel to work without any direct supervision by pharmacists and without any pharmacist being physically present, Merck-Medco flagrantly violates the state regulatory requirements.

91. By failing to comply with regulatory requirements, Merck-Medco has adopted a system that not only violates the law, but, more importantly, fails to achieve the required standard of care, undermining the safety and integrity of their drug dispensing operations and increasing risks to unsuspecting patients. The violations result in Merck-Medco generating greater profits from its pharmacy operations.

92. Had government-funded health insurance programs been aware of the conduct alleged in this complaint, they would not have paid the claims submitted by defendants or paid for the services for which defendants were contracted to provide.

93. Because the Government would not have paid the defendants' claims, defendants concealed their illegal activities from the Government as a means of defrauding Government-funded health insurance programs into paying for claims and services it otherwise would not have paid.

94. At all times relevant to this complaint, it was a violation of federal law to submit, conspire to submit, or cause to be submitted, a false or fraudulent claim for payment or approval by a Government health insurance program.

95. At all times relevant to this complaint, it was a violation of federal law to make, use, conspire to make or use, or cause to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by a Government-funded health insurance program.

96. At all times relevant to this complaint, it was a violation of federal law to conspire to defraud the United States by getting a false or fraudulent claim allowed or paid.

COUNTS ONE AND TWO
False Claims Act
31 U.S.C. § 3729(a)(1) and (a)(2)

97. Relators reallege and incorporate by reference the allegations contained in Paragraphs 1 through 96 of this complaint.

98. This is a claim for treble damages and forfeitures under the False Claims Act, 31 U.S.C. §§ 3729, *et seq.*, as amended.

99. By virtue of the acts described above, defendants knowingly engaged in schemes for the purpose of inducing, and did induce, the presentation of false or fraudulent claims to the United States Government for payment.

100. By virtue of the acts described above, defendants knowingly presented or caused to be presented to the United States Government false or fraudulent claims.

101. By virtue of the acts described above, defendants knowingly made, used or caused to be made or used false records or statements to get a false or fraudulent claim

paid by the United States Government.

102. By virtue of the acts described above, defendants knowingly concealed the existence of their improper conduct from the United States Government in order to induce payment of their false or fraudulent claims.

103. The United States, unaware of defendants' wrongdoing or the falsity of the records, statements or claims made by the defendant or defendants wrongdoing, paid the defendant for claims that would not otherwise have been allowed.

104. By reason of these payments, the United States has been damaged, and continues to be damaged, in substantial amount.

COUNT THREE
False Claims Act
31 U.S.C. §§ 3729(a)(3)

105. Relators reallege and incorporates by reference the allegations made in paragraphs 1 through 104 of this complaint.

106. This is a claim for treble damages and forfeitures under the False Claims Act, 31 U.S.C. §§ 3729, *et seq.*, as amended.

107. By virtue of the acts described above, defendants and their agents knowingly conspired for the purpose of inducing, and did induce, the presentation of false or fraudulent claims to the United States Government for payment.

108. By virtue of the acts described above, defendants knowingly conspired to present or cause to be presented to the United States Government false or fraudulent claims.

109. By virtue of the acts described above, defendants knowingly conspired to

make, use or cause to be made or used false records or statements to get a false or fraudulent claim paid by the United States Government.

110. By virtue of the acts described above, defendants knowingly conspired to conceal the existence of their improper conduct from the United States Government in order to induce payment of their false or fraudulent claims.

111. The United States, unaware of defendants' wrongdoing or the falsity of the records, statements or claims made by the defendant or defendants wrongdoing, paid the defendant for claims that would not otherwise have been allowed.

112. By reason of these payments, the United States has been damaged, and possibly continues to be damaged, in substantial amount.

WHEREFORE, relator requests that judgment be entered in favor of the United States and relator against defendants, ordering that:

a. defendants cease and desist from violating the False Claims Act, 31 U.S.C. § 3729, *et seq.*;

b. defendants pay an amount equal to three times the amount of damages the United States has sustained because of defendants' actions, plus a civil penalty of not less than $5,500, and not more than $11,000 for each violation of 31 U.S.C. § 3729;

c. relator be awarded the maximum amount allowed pursuant to 31 U.S.C. § 3730(d);

d. relator be awarded all costs of this action, including attorneys' fees and costs pursuant to 31 U.S.C. § 3730(d); and

e. the United States and relators recover such other relief as the Court deems just and proper.

By: _____

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February 10, 2000